



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket Nos. FDA-2011-N-0920, FDA-2011-N-0922]

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Definition of Qualified Auditor; Announcement of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the effective date for the definition of qualified auditor in the two final rules that appeared in the Federal Register of September 17, 2015.

DATES: The effective date of paragraph (2) of the definition of qualified auditor in 21 CFR 117.3 and in 21 CFR 507.3, which published in the Federal Register of September 17, 2015 (80 FR 55908) and (80 FR 56170), is [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

For questions relating to Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

For questions relating to Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Jeanette Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

SUPPLEMENTARY INFORMATION:

In the Federal Register of September 17, 2015 (80 FR 55908), we published a final rule for “Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (preventive controls for human food rule). In § 117.3, we included the definition of a qualified auditor. In the definition, we provided examples of qualified auditors. Paragraph 2 of the definition reads “An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.” At the time the final rule published, paragraph 2 referred to a provision in a future final rule: “Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits to Issue Certifications” (third-party certification rule). In the preamble to the preventive controls for human food rule, we stated that we would publish a document in the Federal Register announcing the effective date of paragraph (2) once we finalized the third-party certification rule (80 FR 55908 at 55954).

In the Federal Register of September 17, 2015 (80 FR 56170), we published a final rule for “Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” (preventive controls for animal food rule). In § 507.3, we included the definition of a qualified auditor. In the definition, we provided examples of qualified auditors. Paragraph 2 of the definition reads “An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.” At the time the final rule published, paragraph 2 referred to a provision in a future final rule: “Accreditation

of Third-Party Certification Bodies to Conduct Food Safety Audits to Issue Certifications” (third-party certification rule). In the preamble to the preventive controls for animal food rule, we stated that we would publish a document in the Federal Register announcing the effective date of paragraph (2) once we finalized the third-party certification rule (80 FR 55908 at 55954).

The final third-party certification rule (80 FR 74569) published in the Federal Register on November 27, 2015, with an effective date of January 26, 2016. This document announces that the effective date for paragraph 2 in the definition of qualified auditor in § 117.3 (80 FR 55098 at 56147) and § 507.3 (80 FR 56170 at 56339) is [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: September 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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